

Application Serial No. 07/402,450
Amendment dated 27 December 2011
Reply to Decision on Request for Rehearing dated 26 October 2011

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Claims 1-189 (canceled).

Claim 190 (currently amended): A process for amplification of a target viral RNA and a reference RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;
- (ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;
- (iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence; and
- (iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence.

Claim 191 (previously presented): The process of claim 190, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the selected target viral RNA

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sequence, a sequence not present in the selected target viral RNA sequence and a sequence present in the selected target viral RNA sequence.

Claim 192 (previously presented): The process of claim 190, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 193 (previously presented): The process of claim 190, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 194 (previously presented): The process of claim 190, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 195 (previously presented): The process of claim 194, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 196 (previously presented): The process of claim 195, wherein the label is an isotope or a fluorophore.

Claim 197 (previously presented): The process of claim 194, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 198 (previously presented): The process of claim 197, wherein the label is an isotope or a fluorophore.

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Claim 199 (currently amended): A process for amplification of a target viral RNA and a reference RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;
- (ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;
- (iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;
- (iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence.

Claim 200 (previously presented): The process of claim 199, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the selected target viral RNA sequence, a sequence not present in the selected target viral RNA sequence and a sequence present in the selected target viral RNA sequence.

Claim 201 (previously presented): The process of claim 199, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 202 (previously presented): The process of claim 199, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

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Claim 203 (previously presented): The process of claim 199, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 204 (previously presented): The process of claim 203, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 205 (previously presented): The process of claim 204, wherein the label is an isotope or a fluorophore.

Claim 206 (previously presented): The process of claim 203, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 207 (previously presented): The process of claim 206, wherein the label is an isotope or a fluorophore.

Claim 208 (currently amended): A process for amplification of a target viral RNA sequence and a reference RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence.

Claim 209 (previously presented): The process of claim 208, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the target viral RNA sequence, a sequence not present in the target viral RNA sequence and a sequence present in the target viral RNA sequence.

Claim 210 (previously presented): The process of claim 208, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

Claim 211 (previously presented): The process of claim 208, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 212 (previously presented): The process of claim 208, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 213 (previously presented): The process of claim 212, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 214 (previously presented): The process of claim 213, wherein the label is an isotope or a fluorophore.

Claim 215 (previously presented): The process of claim 212, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 216 (previously presented): The process of claim 215, wherein the label is an isotope or a fluorophore.

Claim 217 (currently amended): A process for amplification of a target viral RNA sequence and a reference RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence if present in the sample and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence.

Claim 218 (previously presented): The process of claim 217, wherein the reference RNA sequence consists of a linear arrangement of a sequence present in the target viral RNA sequence, a sequence not present in the target viral RNA sequence and a sequence present in the target viral RNA sequence.

Claim 219 (previously presented): The process of claim 217, wherein the target viral RNA sequence is a human immunodeficiency virus (HIV) RNA sequence or a human cytomegalovirus (HCMV) RNA sequence.

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Claim 220 (previously presented): The process of claim 217, wherein a primer utilized in the polymerase chain reaction amplification includes a T-7 RNA polymerase binding sequence.

Claim 221 (previously presented): The process of claim 217, wherein the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence are measured by measuring (i) the amount of signal obtained from the amplified target viral RNA sequence and (ii) the amount of signal obtained from the amplified reference RNA sequence.

Claim 222 (previously presented): The process of claim 221, wherein the amounts of the signals are determined by the use of labeled probes.

Claim 223 (previously presented): The process of claim 222, wherein the label is an isotope or a fluorophore.

Claim 224 (previously presented): The process of claim 221, wherein the amounts of the signals are determined by the use of labeled primers in the polymerase chain reaction.

Claim 225 (previously presented): The process of claim 224, wherein the label is an isotope or a fluorophore.

Claims 226-241 (canceled).

Claim 242 (previously presented): The process of claim 190, wherein the sequence not present in the selected target viral RNA sequence is about 21 nucleotides in length.

Claim 243 (previously presented): The process of claim 199, wherein the sequence not present in the selected target viral RNA sequence is about 21 nucleotides in length.

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Claim 244 (previously presented): The process of claim 208, wherein the sequence not present in the selected target viral RNA sequence is about 21 nucleotides in length.

Claim 245 (previously presented): The process of claim 217, wherein the sequence not present in the selected target viral RNA sequence is about 21 nucleotides in length.

Claims 246-248 (canceled).

Claim 249 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;
- (ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;
- (iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;
- (iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and
- (v) determining the relative amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 250 (currently amended): A process for quantitation of a target viral RNA in a sample which comprises:

- (i) selecting a sequence present in the target viral RNA;
- (ii) adding a known quantity of a reference RNA sequence to the sample, wherein the reference RNA sequence comprises a sequence present in the selected target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the selected target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified selected target viral RNA sequence are distinguishable by size or by probes;
- (iii) simultaneously subjecting the selected target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the selected target viral RNA sequence if present in the sample and the reference RNA sequence;
- (iv) measuring the amounts of the amplified selected target viral RNA sequence and the amplified reference RNA sequence; and
- (v) determining the relative amount of the target viral RNA present in the sample before amplification from the amount of the amplified selected target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 251 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the relative amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 252 (currently amended): A process for quantitation of a target viral RNA sequence in a sample which comprises:

combining a known quantity of a reference RNA sequence with the sample, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes;

simultaneously subjecting the target viral RNA sequence and the reference RNA sequence in the sample first to a reverse transcription reaction and then to polymerase chain reaction amplification under conditions appropriate to simultaneously amplify the target viral RNA sequence if present in the sample and the reference RNA sequence;

measuring the amounts of amplified target viral RNA sequence and amplified reference RNA sequence; and

determining the relative amount of the target viral RNA sequence present in the sample before amplification from the amount of the amplified target viral RNA sequence and the amount of the amplified reference RNA sequence.

Claim 253 (currently amended): An amplification reaction mixture for the quantitation of a target viral RNA sequence in a biological sample, said reaction mixture comprising:

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a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.

Claim 254 (currently amended): A reverse transcription reaction mixture for reverse transcribing a target viral RNA sequence suspected of being present in a biological sample, said reaction mixture comprising:

a target viral RNA sequence;

a known quantity of a reference RNA sequence, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified for initiating cDNA synthesis to provide a target viral cDNA and a reference sequence cDNA, whereby following reverse transcription the resulting target viral and reference sequence cDNAs can serve as templates for amplification for providing amplified reference RNA sequence and amplified target viral RNA sequence.

Claim 255 (currently amended): A kit for the quantitation of a target viral RNA sequence in a biological sample comprising individual containers which provide:

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a known quantity of a reference RNA sequence, wherein the reference RNA sequence comprises a sequence present in the target viral RNA sequence and a sequence not present in the selected target viral RNA sequence, wherein the reference RNA sequence and the target viral RNA sequence can be amplified by ~~the same or~~ different oligonucleotides and wherein following amplification amplified reference RNA sequence and amplified target viral RNA sequence are distinguishable by size or by probes; and

an oligonucleotide primer pair for each of the target viral RNA sequence and the reference RNA sequence to be amplified.